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USSN: 10/091,258

Atty. Docket No.: 0213-CIP3-9

1653  
#

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. Serial No.: 10/091,258

Inventors: David R. Hathaway, et al

Filed: March 5, 2002

Title: COMPOSITIONS AND METHODS FOR  
TREATING PERIPHERAL VASCULAR DISEASE

Confirmation No.: 8234

TC/A.U.: 1653

Examiner: LIU, Samuel W.

TRANSMITTAL

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

The following documents are enclosed herewith for your review and consideration:

- Supplemental Information Disclosure Statement (2 pages)
- PTO/SB08 Form (2 pages)
- Fee Transmittal Form (in duplicate) (2 pages)
- List of Prior Art and Other Materials Relied Upon (1 page)
- Six References listed as Prior Art (195 pages)
- Return Receipt Postcard

Respectfully submitted,  
AMYLIN PHARMACEUTICALS, INC.

Dated: March 22, 2006

By:   
Susan J. Myers Fitch  
Registration No. 55,477

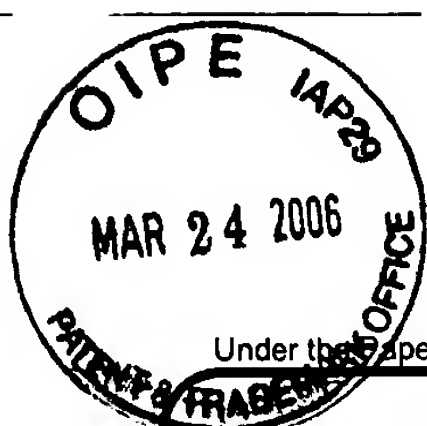
AMYLIN PHARMACEUTICALS, INC.  
9360 Town Centre Drive  
San Diego, CA 92121  
Telephone: 858.552.2200  
Facsimile: 858.552.1936

CERTIFICATE OF MAILING  
(37 C.F.R. §1.8a)

I hereby certify that this paper (along with anything referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage in an envelope addressed to the Commissioner for Patents, Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450, DC 20231

3/22/06  
Date of Deposit

Deborah Wykes  
Name of Person Mailing Paper  
Deborah Wykes  
Signature of Person Mailing Paper



PTO/SB/17 (01-06)

Approved for use through 07/31/2006. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

# FEE TRANSMITTAL

## For FY 2006

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) 180.00

**Complete if Known**

Application Number	10/091,258
Filing Date	March 5, 2002
First Named Inventor	HATHAWAY, David R., et al
Examiner Name	LIU, Samuel W.
Art Unit	1653
Attorney Docket No.	0213-CIP3-9

**METHOD OF PAYMENT (check all that apply)**☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): \_\_\_\_\_☒ Deposit Account Deposit Account Number: 010535 Deposit Account Name: Amylin Pharmaceuticals

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, except for the filing fee☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☒ Credit any overpayments

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**FEE CALCULATION (All the fees below are due upon filing or may be subject to a surcharge.)****1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

**2. EXCESS CLAIM FEES****Fee Description**

Each claim over 20 (including Reissues)

Each independent claim over 3 (including Reissues)

Multiple dependent claims

Fee (\$)	Small Entity Fee (\$)
50	25
200	100
360	180

Total Claims	Extra Claims	Fee (\$)	Fee Paid (\$)
- 20 or HP =	x	=	

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims	Extra Claims	Fee (\$)	Fee Paid (\$)
- 3 or HP =	x	=	

HP = highest number of independent claims paid for, if greater than 3.

**3. APPLICATION SIZE FEE**

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
- 100 =	/ 50 =	(round up to a whole number) x	=	

**4. OTHER FEE(S)**

Non-English Specification, \$130 fee (no small entity discount)

Other (e.g., late filing surcharge): Supplemental Information Disclosure Statement

Fees Paid (\$)

\$180.00

**SUBMITTED BY**Signature [Signature]Registration No. 55,477  
(Attorney/Agent)

Telephone 858-552-2200

Name (Print/Type) Susan J. Myers FitchDate March 22, 2006

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Atty. Docket No.: 0213-CIP3-9

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Appl. Serial No.: 10/091,258

Inventors: David R. Hathaway, et al

Filed: March 5, 2002

Title: COMPOSITIONS AND METHODS FOR  
TREATING PERIPHERAL VASCULAR DISEASE

Confirmation No.: 8234

TC/A.U.: 1653

Examiner: LIU, Samuel W.

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

TO THE COMMISSIONER OF PATENTS AND TRADEMARKS:

In accordance with 37 C.F.R. 1.97 and 1.98 and MPEP 609, and in compliance with the duty of disclosure set forth in 37 C.F.R. 1.56, Applicant submits copies of the references listed on the attached PTO Form PTO/SB/08A for consideration by the U.S. Patent and Trademark Office in the above-entitled application and to be made of record herein. In accordance with 37 C.F.R. 1.98, copies of cited U.S. Patents and U.S. Patent Application Publications are not included herewith.

I certify that each item contained in this Supplemental Information Disclosure Statement was cited in a communication from a foreign patent office regarding a foreign application. A copy of the list of references relied upon is enclosed.

03/27/2006 WABDELRI 00000048 010535 10091258

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Date of Deposit

3/22/06

Signature of Person Mailing Paper

Name of Person Mailing Paper

It is respectfully noted that Applicant is submitting only those references cited in the communication from the foreign office that were not previously submitted with the Information Disclosure Statement filed on April 13, 2005.

The Commissioner is hereby authorized to charge Deposit Account No. 010535 the amount of \$180.00 as set forth in 37 C.F.R. 1.17(p). Applicant believes no additional fees are due. If Applicant is in error, the Commissioner is hereby authorized to charge any underpayment or credit any overpayment to Deposit Account No. 010535. Additionally, the Commissioner is hereby authorized to charge payment or credit overpayment of any fees during the pendency of this application to Applicant's Deposit Account No. 010535.

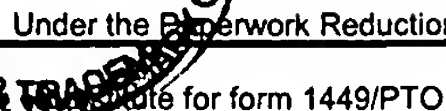
Respectfully Submitted

AMYLIN PHARMACEUTICALS, INC.

Dated: 22 march 2006

  
\_\_\_\_\_  
Susan J. Myers Fitch  
Registration No. 55,477

**AMYLIN PHARMACEUTICALS, INC.**  
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Telephone: (858) 552-2200  
Facsimile: (858) 552-1936



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**(Use as many sheets as necessary)**

Sheet 1

of 2

Application Number	10/091,258
Filing Date	March 5, 2002
First Named Inventor	David R. Hathaway, et al
Art Unit	1653
Examiner Name	LIU, Samuel W.
Attorney Docket Number	0213-CIP3-9

[illegible]

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	01	EP 0708179 A2	04/24/1996	ELI LILLY AND COMPANY		
	02	WO 98/08531 A1	03/05/1998	ELI LILLY AND COMPANY		
	03	WO 00/16797 A2	03/30/2000	ELI LILLY AND COMPANY		

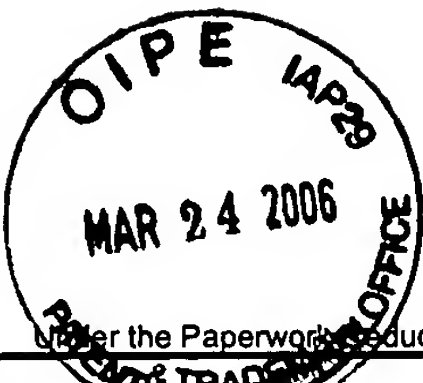
**Examiner  
Signature**

Date  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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PTO/SB/08B (07-05)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/091,258
				Filing Date	March 5, 2002
				First Named Inventor	David R. Hathaway, et al
				Art Unit	1653
				Examiner Name	LIU, Samuel W.
Sheet	2	of	2	Attorney Docket Number	0213-CIP3-9

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	04	DIAZ, Rafael, et al, "Metabolic Modulation of Acute Myocardial Infarction the ECLA Glucose-Insulin-Potassium Pilot Trial", Circulation (1998) pp2227-2234, 98	
	05	RYAN, Thomas J., et al, "ACC/AHA Guidelines for the Management of Patients with Acute Myocardial Infarction" J. Am. Coll. Cardiol. (1996) pp1328-1428, 28	
	06	VOLL, C.L., et al, "Postischemic Insulin Reduces Spatial Learning Deficit Following Transient Forebrain Ischemia in Rats", Stroke (1989) pp 646-651, 20	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



# 1. PRIOR ART AND OTHER MATERIALS RELIED UPON

- D1 (WO 00/16797) WO 00/16797 (Eli Lilly and Company) published on 30 March 2000 (filing date – 22 September 1999; priority date 24 September 1998) Available under Art 54(3) EPC
- D2 Epidos extract for WO 00/16797
- D3 (WO 98/08531) WO 98/08531 (Eli Lilly and Company) published on 5 March 1998. Cited as D1 during examination proceedings
- D4 (Voll *et al.*) Voll *et al.* (1989) *Stroke* **20** p646-651
- D5 (EP 0 708 179) EP 0 708 179 (Eli Lilly and Company) published on 24 April 1996
- D6 (Diaz *et al.*) Diaz *et al.* (1998) *Circulation* **98** p2227-2234
- D7 (Ryan *et al.*) Ryan *et al.* (1996) *J. Am. Coll. Cardiol.* **28** p1328-1428

All page references for the patent under opposition relate to the B specification of the patent as granted, unless otherwise indicated.